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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/780,762 02/09/01 CONNOR

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027407 HM12/0507  
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EXAMINER

CHUNDURU, S

ART UNIT	PAPER NUMBER
1656	g

DATE MAILED:

05/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/780,762	CONNOR ET AL.
	Examiner	Art Unit
	Suryaprabha Chunduru	1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 09 February 2001.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-12 and 18-25 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)  
17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 20)  Other: \_\_\_\_\_

**DETAILED ACTION**

1. The disclosure is objected because of the following informalities:

- (i) the Oath/Declaration is not in permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).
- (ii) The drawings are objected to because the Fig.Nos. 2A, 2B and 3 are not in permanent ink. Correction is required.
- (iii) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 10, paragraph 1 of the specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
- (iv) Claims 13-17 are dependent on improper dependable claim (claims 13-17 are dependent on claim 1 instead of claim 12) and hence are not considered for the examination. Claims 13-17 requires proper dependency.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 is drawn to a full length cDNA sequence. Claim 23 is drawn to a cloned nucleic acid. The claims recite the term "a" which encompass indefinite number of full length cDNA sequences and cloned nucleic acids produced by the claimed methods. The specification teach a method to amplify full length cDNA and a method to clone the nucleic acid of interest and does not support the description of nucleic acid (s), full length cDNA (s) produced by the claimed methods. Specification does not provide any nucleic acid sequences obtained by the claimed methods. Therefore, one skilled in the art would conclude that applicants were not in possession of the claimed nucleic acid (s), full length cDNA (s) because the methods are not representative of the claimed nucleic acid molecules and is insufficient to support the above claims. Hence claims 22 and 23 are rejected under the written description.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

a) Claim 20 is indefinite over the recitation of "capable of hybridizing" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited set of nucleotide primers have the potential to hybridize or do in fact do hybridize the recited gene which is to be amplified. Amendment of the claim to read, for example, "which hybridizes" would obviate this rejection.

#### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10-12, 18, 19, 21-24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kool (USPN. 5,714,320) and in view of Bertioli (PCR Cloning Protocols, vol.67, 233-238, 1997).

Kool teaches a rolling circle method for amplifying single-stranded oligonucleotide wherein he discloses (i) providing circular oligonucleotide as template (see column 4, lines 63-64); (ii) annealing the primer to the circular template to form a primed circular template (see column 4, lines 66-67 and column 5, line 1); (iii) combining the primed circular template with nucleotide triphosphates and a polymerase enzyme to form multiple copies (amplification) of the template (see column 5, lines 1-6);(iv) the present method is capable of sequencing and identification such that the ends are readily identifiable (see column 5, lines 13-15); (v) the target molecule is selected from circular DNA or RNA sequences, or analogs thereof (see column 5, lines 62-66);(vi) the single-stranded circular polynucleotides as templates (see column 6, lines 29-35); (vii) the joining of two ends of single-stranded DNA or RNA is facilitated by the use of DNA ligase or RNA ligase (see column 11, lines 7-20); RNase H can be used for the

cleavage of RNA multimers (see column 14, lines 63-66); determination of sequences of selected population of circular sequences can be carried out by standard methods such as sequencing or cloning (see column 18, lines 5-27). However, they did not teach primer extension, amplification of 3' and 5' ends of nucleic acid molecule or cDNA.

Bertioli teaches a method for rapid amplification of the cDNA ends (RACE) which allows the amplification of either the 5' or 3' end of a specific cDNA starting from mRNA population (see page 233, paragraph 1). He discloses that the method is also used for cloning the remainder of a cDNA using a sequence from an incomplete cDNA obtained by screening a library or from PCR using degenerate primers (see page 233, paragraph 1). He also discloses that the method utilizes reverse transcriptase Superscript which lacks RNase H activity (see page 237, paragraph 5).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the single-strand circular oligonucleotide / or polynucleotide amplification method as taught by Kool with the RACE method to achieve the expected advantage of amplification of 3' and 5' ends of a cDNA and cloning full-length cDNA. The motivation for this would have been an approach to amplify both the ends of cDNA in a single reaction vessel.

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*SC*  
Suryaprabha Chunduru  
May 3, 2001

*W. Gary Jones*  
W. Gary Jones  
Supervisory Patent Examiner  
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*5/4/01*